

WHAT IS CLAIMED IS:

1 1. An apparatus useful for inhibiting blood loss out a puncture site in a
2 blood vessel wall and for indicating the location of a blood vessel comprising:

3 a vent tube including a tubular shaft having a proximal end, a distal
4 end, and a lumen extending longitudinally between the proximal end and the distal
5 end;

6 a control head on the distal end of the vent tube shaft, the control
7 head including a proximal end portion, a distal end portion having a distal port,
8 and a central portion between the proximal end portion and the distal end portion,
9 the control head including a lumen extending from the distal port to the vent tube
10 shaft lumen.

1 2. An apparatus in accordance with Claim 1, wherein the control head
2 proximal end portion is externally tapered.

1 3. An apparatus in accordance with Claim 1, wherein the control head
2 distal end portion is externally tapered.

1 4. An apparatus in accordance with Claim 1, wherein the control head
2 further comprises a hole extending laterally through the control head and
3 communicating the control head lumen with the exterior of the control head.

1 5. An apparatus in accordance with Claim 1, wherein the control head
2 lumen has a substantially constant inner diameter.

1 6. An apparatus in accordance with Claim 1, wherein the control head
2 lumen has an inner diameter larger in the central portion than in the distal portion.

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1 7. An apparatus in accordance with Claim 1, further comprising a
2 tubular shaft positioned around the vent tube shaft, the tubular shaft including a
3 proximal end, a distal end, and a lumen extending longitudinally between the
4 tubular shaft proximal end and the tubular shaft distal end, the inner diameter of
5 the tubular shaft lumen being larger than the outer diameter of the vent tube.

1 8. An apparatus in accordance with Claim 7, wherein the tubular shaft
2 is affixed to the vent tube so as to inhibit relative longitudinal motion of the
3 tubular shaft and the vent tube.

1 9. An apparatus in accordance with Claim 8, further comprising an
2 elastic ring slidably positioned on the exterior of the tubular shaft.

1 10. An apparatus in accordance with Claim 7, wherein the vent tube is
2 slidingly received in the tubular shaft lumen.

1 11. An apparatus in accordance with Claim 7, wherein the tubular shaft
2 further comprises a proximal fluid seal and a distal fluid seal between the vent
3 tube and the tubular shaft.

1 12. An apparatus in accordance with Claim 7, wherein the tubular shaft
2 lumen at the distal end of the tubular shaft has an inner diameter that increases
3 distally.

1 13. An apparatus in accordance with Claim 1, further comprising a
2 wire extending through the vent tube lumen, the wire having an outer diameter
3 less than the vent tube lumen inner diameter.

1 14. A pledget delivery and blood vessel puncture site control system
2 comprising:
3 a control tip including:
4 a vent tube having a tubular shaft with a proximal end, a
5 distal end, and a lumen extending longitudinally between the proximal end and the
6 distal end;

7 a control head on the distal end of the vent tube shaft, the
8 control head including an externally tapered proximal end portion, a distal end
9 portion having a distal port, and a central portion between the proximal end
10 portion and the distal end portion, the control head including a lumen extending
11 from the distal port to the vent tube shaft lumen;

12 a pledget pusher positioned around the vent tube shaft, the pledget
13 pusher including a tubular shaft having a proximal end, a distal end, and a lumen
14 extending longitudinally between the pledget pusher proximal end and the pledget
15 pusher distal end, the inner diameter of the pledget pusher lumen being larger than
16 the outer diameter of the vent tube;

17 a delivery cannula positioned around the pledget pusher, the
18 delivery cannula including a tubular shaft having a proximal end, a distal end, and
19 a lumen extending longitudinally between the delivery cannula proximal end and
20 the delivery cannula distal end, the inner diameter of the delivery cannula lumen
21 being larger than the outer diameter of the pledget pusher;

22 the control head extending distally from the delivery cannula distal
23 end, the delivery cannula distal end extending distally of the pledget pusher distal
24 end.

- 1 15. A system in accordance with Claim 14, wherein the control head is
2 sized to be slidable through the delivery cannula lumen.

1 16. A system in accordance with Claim 14, further comprising a
2 pledget positioned in the delivery cannula lumen distal of the pledget pusher distal
3 end.

1 17. A system in accordance with Claim 14, further comprising a handle
2 having a proximal end and a distal end, the handle and the control tip together
3 further comprising a motion limiting device, portions of the motion limiting device
4 being formed on the vent tube adjacent the vent tube proximal end, and portions of
5 the motion limiting device being formed on the handle proximal end, the motion
6 limiting device limiting longitudinal motion of the vent tube relative to the handle
7 over a distance X.

1 18. A system in accordance with Claim 17, wherein the control head
2 extends distally from the delivery cannula distal end the distance X.

1 19. A system in accordance with Claim 17, wherein the pledget pusher
2 further comprises a proximal hub positioned in the handle, wherein the pledget
3 pusher is slidable in the delivery cannula between a proximal position with the
4 pledget pusher proximal hub engaging the vent tube portions of the motion

5 limiting device, and a distal position with the pledget pusher proximal hub
6 engaging the handle distal end.

1 20. A system in accordance with Claim 14, further comprising a handle
2 having a proximal end and a distal end, the handle including a distal hub, wherein
3 the delivery cannula includes a proximal hub, the handle distal hub and the
4 delivery cannula proximal hub including mating structures which releasably hold
5 the handle and the delivery cannula together.

1 21. A system in accordance with Claim 14, further comprising a handle
2 having a proximal end, a distal end, at least one side extending between the handle
3 proximal end and the handle distal end, and an open space adjacent to the at least
4 one side, the pledget pusher including a proximal hub positioned in the handle
5 open space.

1 22. A system in accordance with Claim 21, wherein the pledget pusher
2 is slidable in the delivery cannula between a proximal position and a distal
3 position with the pledget pusher proximal hub engaging the handle distal end.

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1 23. A system in accordance with Claim 14, wherein the pledget pusher
2 distal end includes a countersunk taper having a taper angle substantially the same
3 as the taper angle of the control head externally tapered proximal end portion.

1 24. A system in accordance with Claim 14, further comprising a
2 pledget hydration device having body with a proximal end, a distal end, an
3 interior chamber, a tubular extension extending from the body distal end, a stop
4 adjacent the tubular extension, and a proximal opening, the tubular extension sized
5 to receive the delivery cannula therein, the stop sized and configured to prevent
6 the delivery cannula from entering the interior chamber and sized and configured
7 to permit the pledget pusher and control head to pass into the interior chamber.

1 25. A method of positioning a pledget adjacent to the exterior surface of
2 a blood vessel puncture site in a patient, comprising the steps of:

3 advancing a control head of a control tip through the puncture site
4 and at least partially into the blood vessel, the control tip including a proximal
5 portion extending out of the puncture site and out of the patient;

6 advancing an assembly over the control tip proximal portion and
7 adjacent to an exterior surface of the blood vessel, the assembly including a
8 delivery cannula having a lumen, a pledget pusher in the delivery cannula, and a
9 pledget in the delivery cannula

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10 proximately retracting the control head; and
11 expelling the pledget from the delivery cannula.

1 26. A method in accordance with Claim 25, wherein the step of
2 proximately retracting the control head comprises engaging the pledget with the
3 control head.

1 27. A method in accordance with Claim 25, wherein the step of
2 proximately retracting the control head comprises engaging the blood vessel
3 puncture with the control head.

1 28. A method in accordance with Claim 25, wherein the steps of
2 advancing the control head and advancing the assembly are performed
3 simultaneously.

1 29. A method in accordance with Claim 25, wherein the step of
2 advancing the control head is performed before the step of advancing the
3 assembly.

1 30. A method in accordance with Claim 25, further comprising the step
2 of:

3 proximally retracting the delivery cannula and the control tip
4 relative to the puncture site and relative to the pledget pusher.

1 31. A method in accordance with Claim 30, further comprising the step
2 of:

3 proximally retracting the control tip relative to the puncture site and
4 relative to the pledget pusher.

1 32. A method in accordance with Claim 30, wherein the expelling step
2 further comprises the step of distally advancing the pledget pusher to push the
3 pledget out of the delivery catheter.

1 33. A method in accordance with Claim 32, further comprising
2 proximally retracting the control head and the pledget pusher relative to the
3 delivery cannula, the control head being retracted through the pledget, the delivery
4 cannula distal end engaging the pledget.

1 34. A method in accordance with Claim 33, wherein the expelling step
2 further comprises the step of distally advancing the pledget pusher to compress the
3 pledget.

1 35. A method in accordance with Claim 25, wherein the control tip
2 includes a fluid flow path from the control head to the proximal end of the
3 proximal portions, and further comprising stopping the step of advancing the
4 control head after blood from the blood vessel has traveled along the fluid flow
5 path to the control tip proximal end.

1 36. A method in accordance with Claim 35, further comprising
2 stopping the step of advancing the assembly after distal portions of the assembly
3 bump into the blood vessel wall.

1 37. A method in accordance with Claim 25, wherein the step of
2 advancing the control tip and the step of advancing the assembly are performed
3 simultaneously.

1 38. A method of measuring the distance between an epidermal outer
2 surface and the outer surface of a blood vessel, the blood vessel having a puncture
3 therethrough at a puncture site, comprising the steps of:

4 advancing a control tip through subcutaneous tissue and into the
5 blood vessel through the puncture;

6 advancing a tubular shaft over the control tip until a distal end of
7 the tubular shaft engages the outer surface of the blood vessel; and

8 positioning a marker along the tubular shaft against the epidermal
9 outer surface.

1 39. A method in accordance with Claim 38, wherein the step of
2 advancing the control tip and the step of advancing the tubular shaft are performed
3 simultaneously.

1 40. A method in accordance with Claim 38, wherein the step of
2 advancing the control tip is performed before the step of advancing the tubular
3 shaft.

1 41. A method in accordance with Claim 38, wherein the step of
2 advancing the control tip is stopped after blood from the blood vessel flashes out a
3 proximal end of the control tip.

1 42. A method in accordance with Claim 38, wherein the step of
2 advancing the tubular shaft is stopped when distal portions of the tubular shaft
3 bump into the blood vessel wall.

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1 43. A method in accordance with Claim 38, wherein the step of
2 advancing the tubular shaft is stopped when blood from the blood vessel flashes
3 out a proximal end of the tubular shaft.

1 44. A method of at least partially controlling blood flow through a
2 puncture site in a blood vessel wall, comprising the steps of:
3 inserting a control tip through the vessel wall at the puncture site
4 and at least partially into the blood vessel; and
5 positioning a pledget adjacent to an outer surface of the blood
6 vessel wall at the puncture site with the control tip still at least part in the vessel
7 puncture site.

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